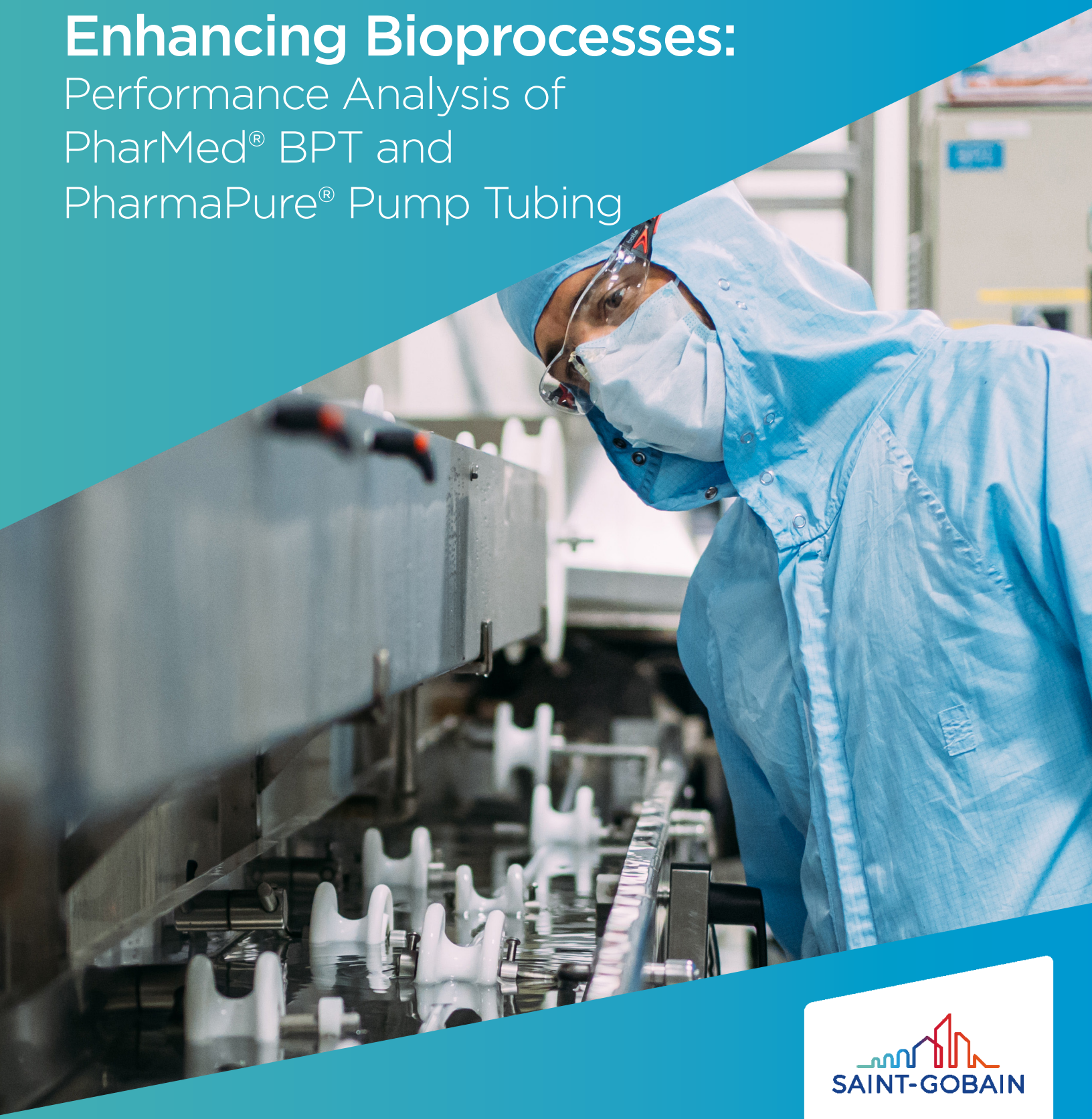
WHITE PAPER 0133

Enhancing Bioprocesses:

Performance Analysis of PharMed® BPT and PharmaPure® Pump Tubing



SAINT-GOBAIN

BIOPROCESS SOLUTIONS

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PharMed® BPT and PharmaPure® are premier choices for critical pumping applications where reliability, longevity, and purity are paramount.

INTRODUCTION

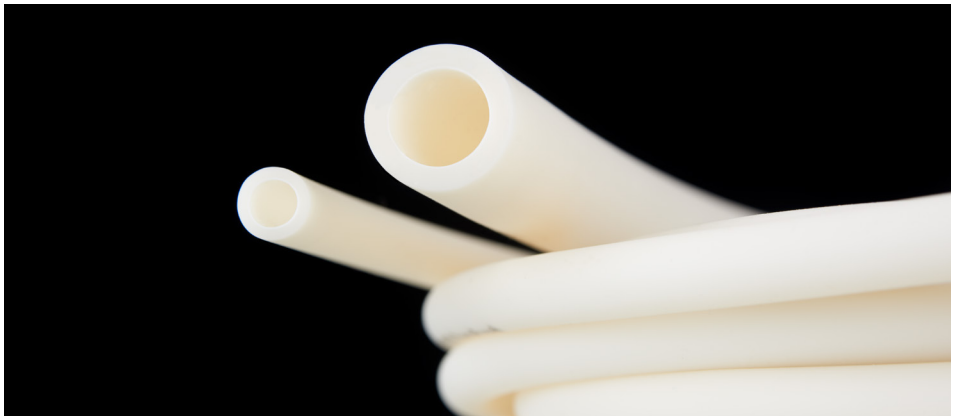
Saint-Gobain Bioprocess Solutions' PharMed® BPT and PharmaPure® tubing are thermoplastic elastomer (TPE) tubing products engineered for reliable performance in peristaltic pumps for critical pharmaceutical and biopharmaceutical applications. This white paper highlights the exceptional performance of these tubes, focusing on pump life, burst pressure, spallation, bend radius, and other relevant factors. The results demonstrate how each tubing family performs under conditions relevant to single-use bioprocessing and fluid-transfer systems.

GUIDANCE TABLE

Tubing Type	PharMed® BPT	PharmaPure®
Pump Life	+++++	+++++
Burst Pressure	+++	+++
Low Spallation	++	++++
Vacuum	Yes	Yes
Chemical Resistance	+++++	+++++
Permeability	Low	Low

Key:
+ = Fair
++ = Good
+++ = Great
++++ = Excellent
+++++ = Superior

PharMed® BPT tubing family



PharmaPure® tubing family

SUMMARY OF PHARMED® BPT AND PHARMAPURE® PERFORMANCE

Pump Life

- PharMed® BPT and PharmaPure® tubing demonstrate excellent durability, with average pump life exceeding 1,000 hours – even under backpressure conditions.

Burst Pressure

- Both materials provide high burst pressure, supporting safe and reliable operation in demanding applications.

Spallation

- PharmaPure® shows lower spallation compared to PharMed® BPT (and other TPE tubing), reducing the risk of particle generation during fluid transfer. This is especially beneficial for applications requiring higher purity.

Chemical Resistance

- Both materials consistently achieved excellent chemical resistance ratings, showcasing broad compatibility with biopharmaceutical solutions. See the Saint-Gobain Chemical Compatibility Guide for more information.

Bend Radius

- Minimum bend radius is comparable to other TPE tubing, making both materials suitable for a wide range of system configurations.

Other Performance Factors

- Low-temperature Flexibility and Impact Resistance: Both materials passed low-temperature (LT) flexibility at –55 °C and impact transitioned around -67 °C.
- Permeation Resistance: PharMed® BPT and PharmaPure® both exhibit low permeation properties.
- Pinch valve performance: Both tubing types showed excellent performance, consistently reopening immediately after clamp release.
- Optical properties: These materials demonstrated the highest opacity providing superior light protection for light-sensitive fluids.
- Vacuum resistance: Both tubes showed excellent results, with no tube exceeding a 20% OD change at full vacuum.

CERTIFICATIONS

PharMed® BPT and PharmaPure® prioritize safety and biocompatibility, evidenced by their comprehensive certifications. Both tubing types are notably free of phthalates, bisphenol A, and animal derivatives (ADCF), making them a preferred choice for sensitive biopharma applications. Furthermore, these tubes meet stringent industry standards, adhering to USP <88> Class VI, and/or USP <87>, and/or ISO 10993-5 USP certifications. For more details on these certifications, please consult the validation guides found on our Saint-Gobain Bioprocess Solutions website.

MATERIAL SELECTION

Two of Saint-Gobain Bioprocess Solutions' top-tier TPE tubing products, PharMed® BPT and PharmaPure®, were tested for application-specific testing for benchmarking before and after sterilization.

Tubing Sizes Tested:

- 2/32" wall thickness: 1/4" ID x 3/8" OD
- 3/32" wall thickness: 1/4" ID x 7/16" OD
- 4/32" wall thickness: 1/2" ID x 3/4" OD

Tubing Tested As:

- As-manufactured (Non-sterilized)
- Post-Autoclave (121°C for 30 minutes)
- Post-Gamma Irradiation (40-50 kGy)

PUMP LIFE PERFORMANCE

Pump life testing was conducted using Cole-Parmer MasterFlex™ L/S™ Standard Digital Drive 07522-20 pump drives equipped with Masterflex™ L/S™ Standard Model 7017-21 pump heads. A tubing size of 1/4" inner diameter (ID) by 3/8" out diameter (OD) was used.

The test setup involved circulating tap water through a tubing sample. Inlet and outlet tubing connected the samples to the pump, with a pressure gauge positioned along the outlet flow path measuring back pressure by flow restriction. The test was run with either 0 psi or 10 psi of backpressure at 300 RPM. Samples were continuously pumped until failure, which was defined as a leak in the tubing specimen. Additional burst pressure data for as-manufactured tubing can be found on the datasheets.

Table 1: Pump life testing stopped at 1250 hours

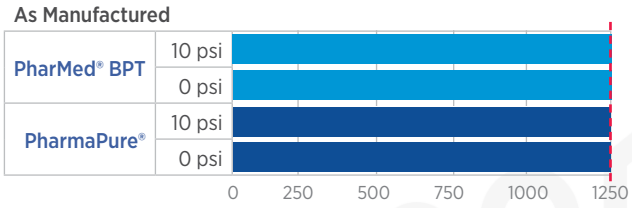


Table 2: Pump life testing stopped at 4000 hours

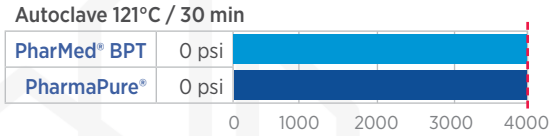


Table 3: Pump life testing stopped at 1500 hours

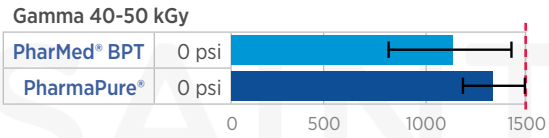
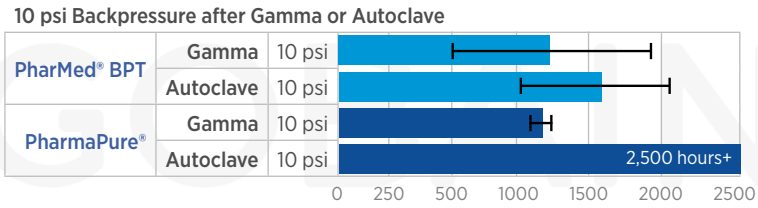


Table 4: Pump life test (hours)



RESULTS

PharMed® BPT and PharmaPure® tubing both demonstrate excellent pump life performance. The data shows that backpressure is the primary driver of reduced pump life, followed by the effects of sterilization. Both PharMed® BPT and PharmaPure® under 10 psi of backpressure and sterilization maintain average pump lives greater than 1,000 hours.

Previous work (Precision Final Fill Pump Tubing white paper) has shown that pump heads with more rollers subject the tubing to increased compression (occlusion), which accelerates tubing fatigue and reduces overall tube life. This test was performed with a 4-roller pump head. In contrast, the L/S Easy-Load® pump head uses 3 rollers which would have approximately 33% longer pump life.

BURST PRESSURE

Burst pressure is the resistance of tubing to hydraulic pressure. Burst pressure is performed at room temperature following ASTM D1599. A Blue M® burst chamber was used with water at room temperature (18-21°C). Failure is defined by either burst or ballooning of the tube, with the test seeing the maximum pressure reached at failure that is defined as burst pressure.

Table 5: Burst pressure for PharMed® BPT tubing

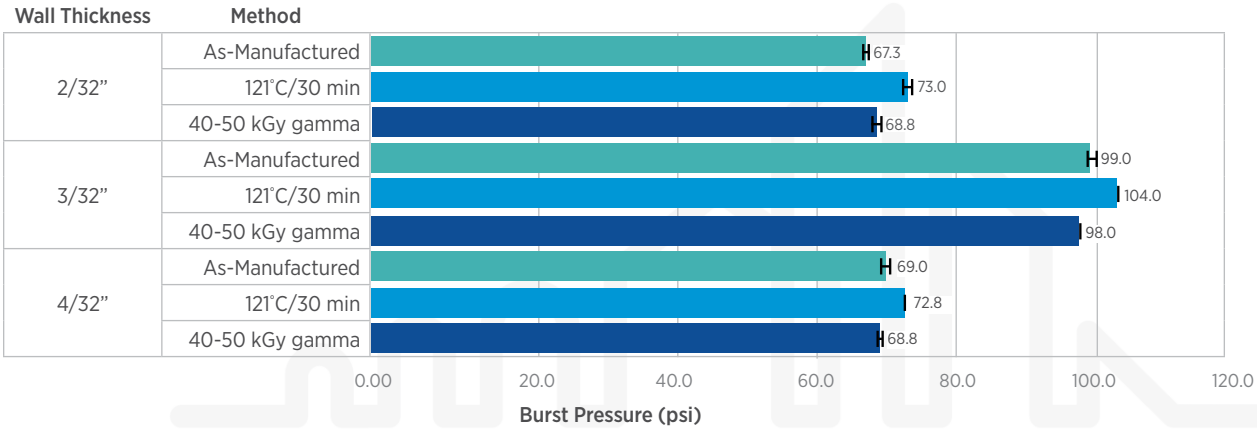
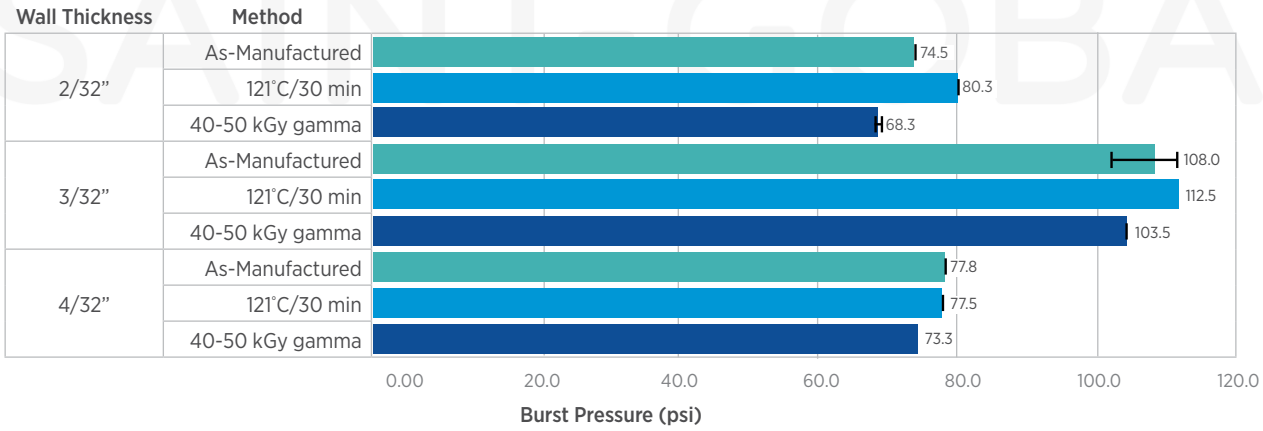


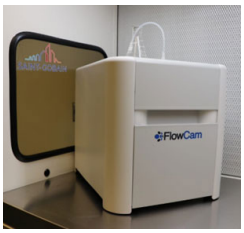
Table 6: Burst pressure for PharmaPure® tubing

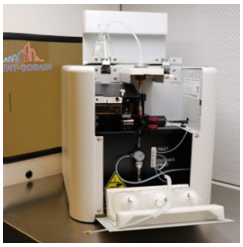


RESULTS

PharMed® BPT and PharmaPure® tubing were tested for burst pressure after different sterilization conditions. Sterilization was shown to have little effect on burst pressure across three different wall thicknesses. Burst pressure varies with tubing geometry. Larger internal diameters resulted in lower burst strength due to increase hoop stress, even with increasing wall. The hoop stress quotient (OD^2+ID^2)/(OD^2-ID^2) increases with a decrease in burst pressure. The hoop stress quotient (HSQ) for 3/32" wall (1/4"x7/16") is 1.97. HSQ for 4/32" wall (1/2"x3/4") is 2.60, so with increasing HSQ burst pressure decreases.

SPALLATION





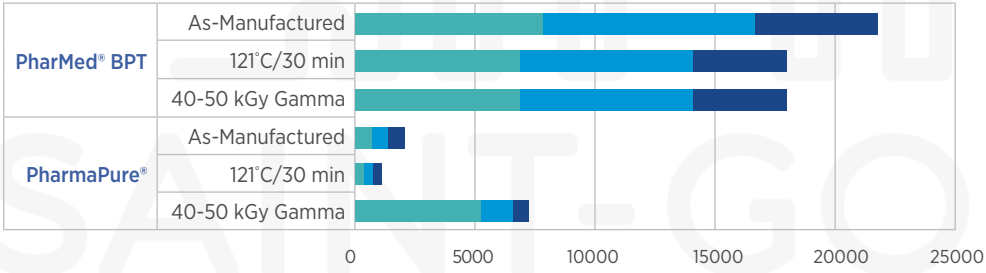
Spallation (or particle shedding) results from the shear-compression force in a peristaltic pump causing the release of particles from tubing.

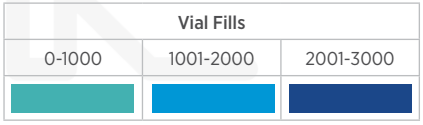
1/16" x 3/16" tubing was loaded on to a 2x6 roller peristaltic pump head at 300 RPM and 100mL of water was recirculated for 1,000 vial fills of 1.8mL, then a total of 2,000 vial fills of 1.8mL, and then to a total of 3,000 vial fills of 1.8mL. 5,400mL of water was recirculated through the pump tube at the end of the experiment. The water was imaged through a flow cytometer where the equipment is able to obtain a particle count and size for all particles in the fluid path.

Spallation was analyzed using flow imaging microscopy (FIM). FlowCam™ 8000 (Yokogawa Fluid Fluid-Imaging Technologies) is a flow imaging cytometer (particle counter) and particle analyzer that is paired with image analysis software VisualSpreadsheet® Particle Analysis Software Version 4. A flowrate of 5mL/min was used with a magnification of 4x. No size filter and an auto image rate of 50 frames/second was used. The flow cell (FC300FV) had a 300 µm flow cell depth and a 1500 µm flow cell width.

Table 7: Total particles/mL 2-10µm

300 RPM, 2x6 roller, 3,000 total vial fills at 1.8mL

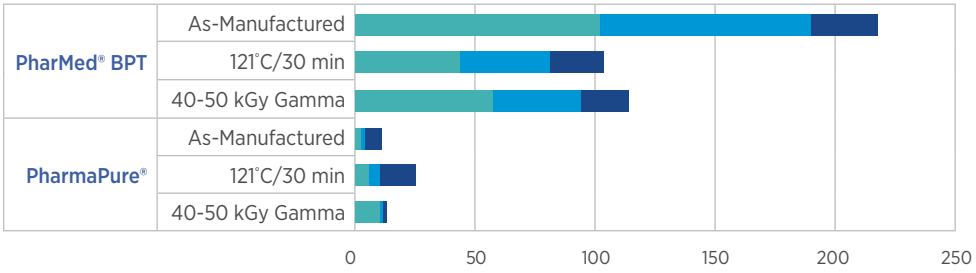


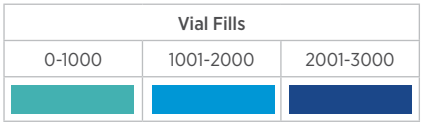


Color is representative of the number of vial fills performed in the graph on the left, which shows the amount of spallation after each 1,000 vial fills and the total amount of spallation.

Table 8: Total particles/mL >10um

300 RPM, 2x6 roller, 3,000 total vial fills at 1.8mL





Color is representative of the number of vial fills performed in the graph on the left, which shows the amount of spallation after each 1,000 vial fills and the total amount of spallation.

RESULTS

The two graphs above highlight the total number of particles/mL collected during spallation testing in two different size ranges: particles from 2-10 µm, and particles greater than 10 µm. Flow imaging microscopy (FIM) used to collect these measurements may detect oil droplets, present in thermoplastic elastomer tubes as a processing aid, which can be included in particle counts and should be considered when interpreting results.

Overall, PharmaPure® sees lower spallation than PharMed® BPT for either particle size range being investigated, making it ideal for applications where low spallation is paramount. For both tube types, the large majority of particles are in the smaller size range. The number of particles being detected as the experiment continues (i.e. reaches larger vial fill counts) continues to decrease, indicating that most particles come off at the beginning of tube usage.

CHEMICAL RESISTANCE

For PharMed® BPT and PharmaPure® information on chemical resistance, consult our Chemical Compatibility Guide for recommendations on which chemicals are rated as Excellent, Good, Fair, or Not Recommended for use with PharMed® BPT and PharmaPure® tubing.

LOW TEMPERATURE FLEXIBILITY AND IMPACT RESISTANCE

Low temperature flexibility testing was adapted from ASTM D 380, Section 25, "Low-Temperature Test on Complete Hose." For each sample type tested, four specimens were cut to a length of 20" and placed into a freezer set to -55 °C. After 72 hours, the specimens were removed one at a time and immediately bent around a mandrel, appropriately sized based on the size of the tubing. Each specimen was given a pass/fail grade upon wrapping around the mandrel: a failing grade was given if the specimen show evidence of cracking or fracturing after visual inspection, while a passing grade meant that the specimen show no evidence of cracking or fracturing after visual inspection. Specimens with indeterminate results were further tested via hydrostatic pressure testing to confirm the presence or lack of cracks allowing system leakage after bending. All specimens tested passed the low temperature flexibility test.

Low temperature impact resistance, testing was adapted from ASTM D 746, "Standard Test Method for Brittleness Temperature of Plastics and Elastomers by Impact." Samples were cooled to a pre-determined temperature using methanol and conditioned for three minutes before testing. Methanol is the recommended heat transfer medium (or coolant) for chilling the test specimens to the desired temperature before impact testing. Samples were then placed in a clamping device and subjected to a single strike from the testing device. The number of failures (specimens that broke upon impact of the testing device) was recorded, along with the temperature of the specimens after conditioning. The brittle point temperature was then calculated based on the percentage of failures experienced at each tested temperature, as described in ASTM D 746. All calculated brittle point temperatures can be seen below.

Table 9: ASTM D 746 "Standard Test Method for Brittleness Temperature of Plastics and Elastomers by Impact"

Brittle points (the temperature at which the material's behavior transitions from ductile to brittle) for PharMed® BPT and PharmaPure® samples, each in three different sterilization states.

	Brittle Point (°C)		
	Unsterilized	Autoclaved	Gamma
PharMed® BPT	-69	-71	-67
PharmaPure®	-67	-68	-67

Table 10: ASTM D 380 "Low Temperature Flexibility Testing"

PharMed® BPT and PharmaPure® in 2/32", 3/32" and 4/32" wall thicknesses pass low temperature flexibility.

	Low Temperature Flexibility		
	Unsterilized	Autoclaved	Gamma
PharMed® BPT	Pass	Pass	Pass
PharmaPure®	Pass	Pass	Pass

RESULTS

PharMed® BPT and PharmaPure® tubing can be used in similar low temperature ranges, regardless of sterilization state. Both tubes passed the low temperature flexibility test at -55°C, and showed similar brittle point performance, transitioning from ductile to brittle behavior around -67°C.

PINCH VALVE USAGE

Pinch valve behavior was assessed in various PharMed® BPT and PharmaPure® tubing sizes (1/4" ID by 3/8" OD, 1/4" ID by 7/16" OD, and 1/2" ID by 3/4" OD) across three sterilization conditions: as-manufactured, post-autoclave, and post-gamma irradiation. For each sample, 5' lengths were marked at 15 points and initial outer diameters recorded. Pure-Fit® TC clamps (PFTC375 for 2/32" wall thickness, PFTC750 for 3/32" and 4/32") were applied at each mark. After 24 hours, the first clamp was removed, and a timer started if the tubing remained pinched. Time to self-opening, removal time, and post-opening outer diameter were recorded. This process was repeated every 24-48 hours for each subsequent clamp.

Testing Evaluated

- Likelihood of immediate self-opening
- Time to self-opening if delayed
- Permanent deformation (change in outer diameter)

RESULTS

In terms of the tubing's likelihood to immediately open after clamp removal, PharMed® BPT and PharmaPure® were excellent performers: no sample, of any size or sterilization type, stayed shut for any amount of time after the clamp was removed. In addition, no deformation was detected for either tube, and fluid path had been completely restored.

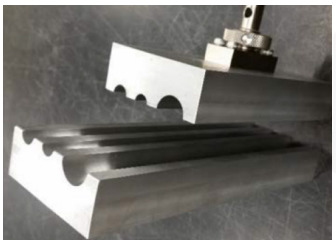
MINIMUM BEND RADIUS

The minimum bend radius (MBR) is the smallest radius the tubing can bend before kinking. This is the point at which liquid would theoretically no longer be able to flow through the tube.

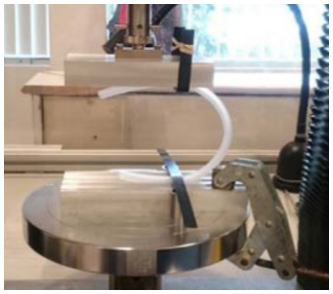
An Instron was used to precisely measure the minimum bend radius. Tubing was loaded in to a fixture to hold the tubing stationary while the Instron upper crosshead moved downward toward the bottom plate, until the tube kinked. The minimum bend radius was calculated using the starting distance between the fixtures and the distance between fixtures at the kinking point. Four specimens were tested per sample type, with the average minimum bend radius being reported.

The average minimum bend radius is presented below on three different sizes of PharMed® BPT and PharmaPure® tubing looking at the effect of both irradiation and autoclave:

- 2/32" wall thickness: 1/4" ID x 3/8" OD
- 3/32" wall thickness: 1/4" ID x 7/16" OD
- 4/32" wall thickness: 1/2" ID x 3/4" OD



Machined fixture that is grooved for holding tubing samples of various sizes in place.



Tube loaded into the Instron before the start of the test.

Table 11: PharMed® BPT Tubing Minimum Bend Radius (MBR)

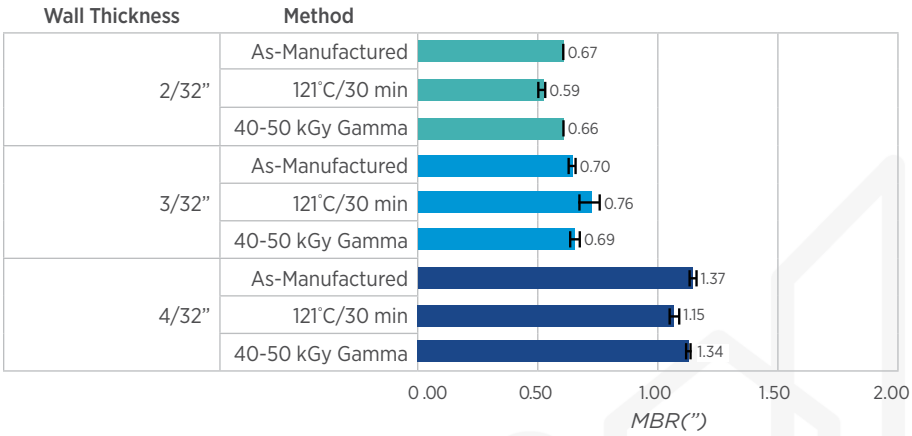
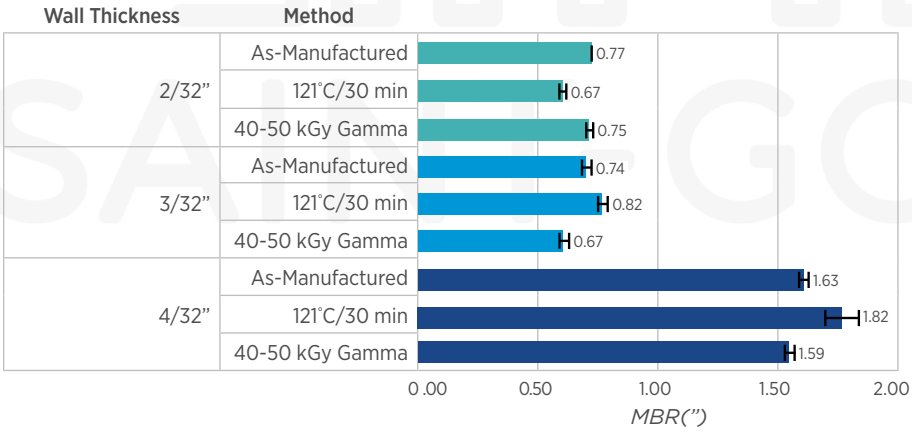


Table 12: PharmaPure® Tubing Minimum Bend Radius (MBR)



RESULTS

The minimum bend radius is not significantly affected by gamma or autoclaving, assuring normal liquid flow.

OPTICAL TRANSMISSION AND YELLOWNESS

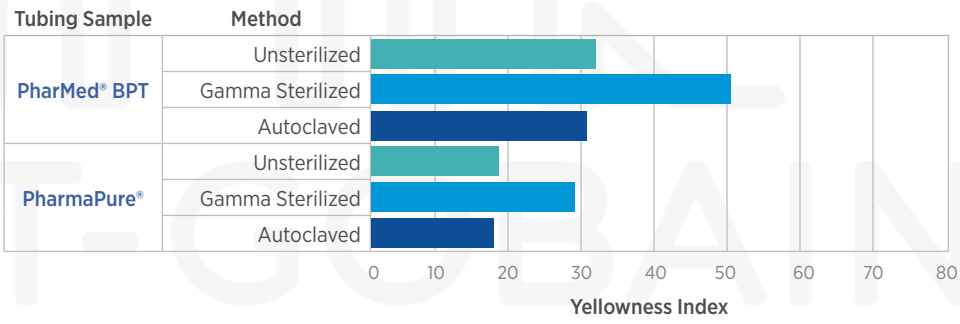
Tubing of size 1/2" ID by 3/4" OD (4/32" wall thickness) was cut to a length of approximately 2" and split open to imitate a plaque roughly 2" by 2" in size when flattened. Each tube type was tested: as-manufactured, post-autoclave treatment, and post-gamma irradiation.

A Hunter Lab UltraScan PRO Spectrophotometer was used to carry out this testing. Sample "plaques" prepared as described above were loaded into the spectrophotometer and subjected to testing over the light wavelength range of 350 nm to 1050 nm. Five specimens were tested for each brand/sterilization type. Y values, a measure of brightness as part of the CIE Tristimulus XYZ color scale, were measured for the material when backed by a white backing material, as well as when backed by a black backing material. Opacity values were then calculated using a ratio between these two Y values. Yellowness index values (YI E313, per ASTM D E313) were also recorded for each sample tested.

The left column of tubing samples is PharMed® BPT, and the right column is PharmaPure®. The top specimen in each column is the tubing in an unsterilized state; the middle specimen, post-gamma irradiation; and the bottom specimen, post-autoclave treatment.

Table 13: Yellowness index

Both PharMed® BPT and PharmaPure® exhibit virtually no yellowness change after autoclaving. An increase in yellowness is seen after gamma sterilization, but high opacity for both tube types provides protection of the tube's contents from UV effects.



VACUUM RESISTANCE

Vacuum resistance was measured across three tubing sizes (1/4" ID by 3/8" OD, 1/4" ID by 7/16" OD, and 1/2" ID by 3/4" OD) of PharMed® BPT and PharmaPure®. Tubing was measured as-manufactured, post-autoclave at 121 °C for 30 minutes, and post-gamma 40-50 kGy.

Following the protocol, 24" tube samples were marked at 8", 12", and 16" for outer diameter (OD) measurements. Initial OD and inner diameter (ID) were recorded. Samples were connected to a vacuum pump (29 inHg capacity) and sealed at the other end. The vacuum was incrementally increased in 5 inHg steps, with a 5-10 minute conditioning period at each level. OD was measured at each mark after conditioning, rotating the micrometer for consistency. Testing continued until full vacuum (-29.9 inHg). Percent ID change (collapse) was calculated from initial ID and OD changes, assuming OD change equals ID change.

Table 14: Vacuum resistance 2/32" wall thickness

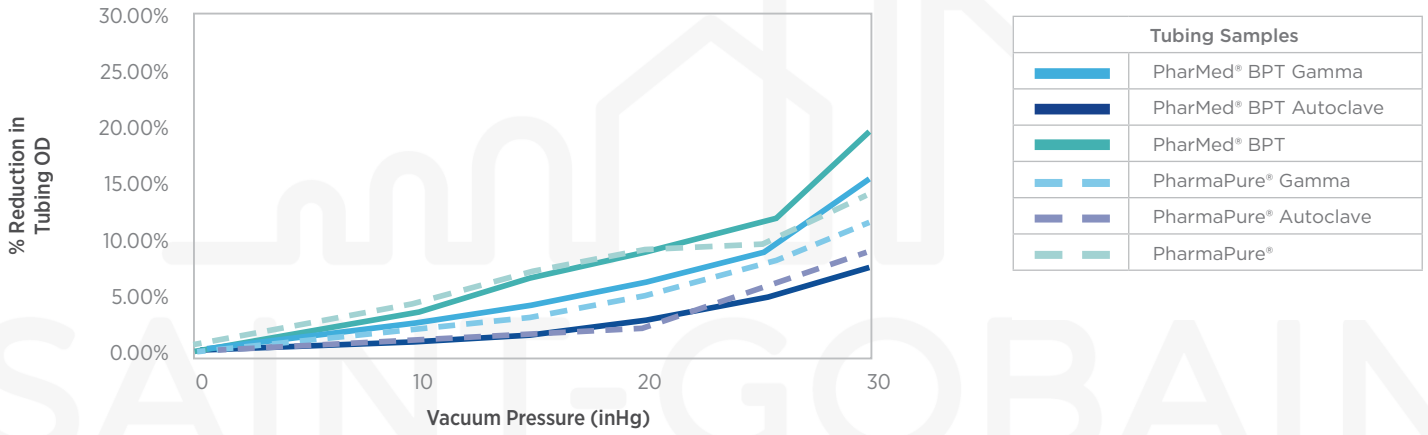


Table 15: Vacuum resistance 3/32" wall thickness

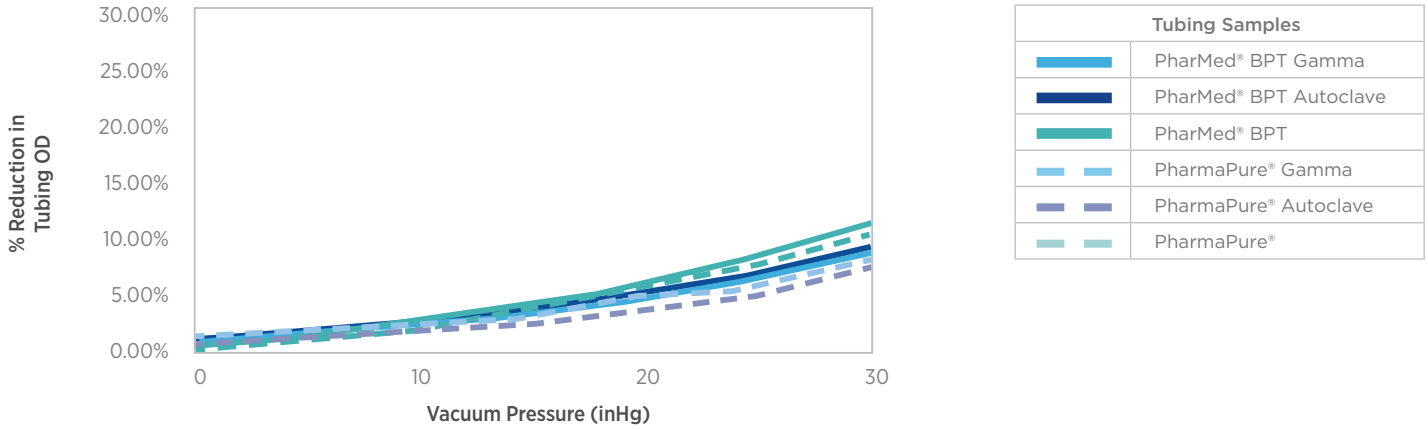
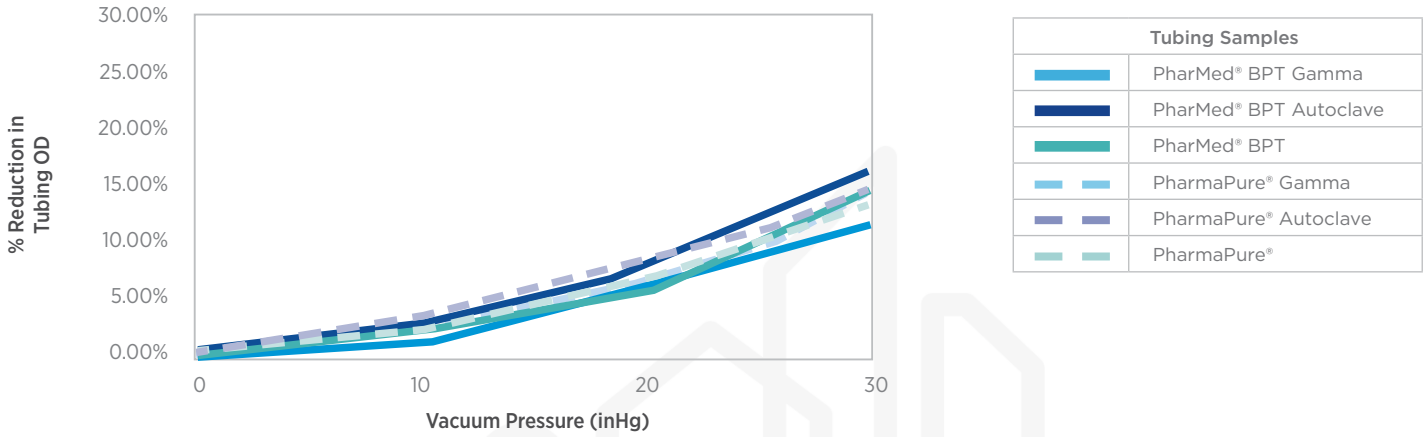


Table 16: Vacuum resistance 4/32” wall thickness



RESULTS

A 30% reduction in tubing diameter or higher is a failure, as flow through the tube would be significantly impacted at those collapse levels. In this test, neither PharMed® BPT nor PharmaPure® exceeded an average of 10% diameter collapse for the three different wall thicknesses tested. Sterilization had either no effect on vacuum resistance or it improved the resistance.

THERMAL WELDABILITY

Thermal weldability is a critical attribute for tubing used in biopharmaceutical manufacturing, enabling sterile connections and system integrity in single-use assemblies. PharMed® BPT has historically been recognized as weldable within the industry, while PharmaPure® has not been broadly recognized for this capability. Internal validation was conducted to assess the weldability of both tubing types using standardized industry methods.

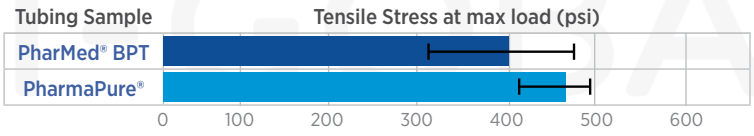
Three welded specimens of PharMed® BPT tubing (left) and PharmaPure® tubing (right) in 1/4" ID x 3/8" OD in size.

RESULTS

Both PharMed® BPT and PharmaPure® tubing (1/4" ID x 3/8" OD) were successfully thermally welded using a Sartorius BioWelder TC system. The PharMed® setting was used for PharmaPure® with the Sartorius welder. All samples passed visual inspection (no defects or irregularities) and pressure integrity testing (no leaks at 1 bar / ~15 psi). These results confirm that welded joints maintain sufficient mechanical integrity for typical processing conditions.

Table 17: Tensile stress values for welded tubes

Tensile stress values for welded tubes for all tubing evaluated as part of this study.



PharMed® BPT and PharmaPure® tubing demonstrate strong thermal weldability, with excellent weld integrity and mechanical performance exceeding industry benchmarks. The Sartorius welder provides good alignment with no concerns for misalignment of the OD coming in contact with the fluid path. These results support the use of both materials in sterile welding applications, enhancing their suitability for advanced single-use bioprocessing systems while expanding design flexibility for end users.

CONCLUSION

PharMed® BPT and PharmaPure® consistently excelled across all performance parameters, showcasing their exceptional suitability as pump tubing for demanding biopharmaceutical applications. PharMed® BPT and PharmaPure® are premier choices for critical pumping applications where reliability, longevity, and purity are paramount. Their consistent performance, even after sterilization, ensures uninterrupted operations and minimizes risks, making them invaluable assets in pharmaceutical and biopharmaceutical manufacturing. PharmaPure® is the optimal tubing for applications sensitive to contamination, where low spallation is critical.

KEY FINDINGS:

Pump Life
- PharMed® BPT and PharmaPure® exhibit outstanding pump life, lasting over 1,000 hours after sterilization.

Burst Pressure
- Consistently met or exceeded requirements, highlighting their robust mechanical integrity.

Spallation
- PharmaPure® exhibited minimal spallation, minimizing contamination risks.

Chemical Resistance
- See the Saint-Gobain Chemical Compatibility Guide that shows PharMed® BPT and PharmaPure® have excellent resistance to a wide variety of solvents and liquids.

Pinch Valve Usage
- Immediate self-opening and complete fluid path restoration were observed, even after prolonged clamping.

Thermal Welding
- PharMed® BPT and PharmaPure® demonstrate strong thermal weldability, supporting use in sterile welding and single-use system integration.

Other Attributes
- Excellent low-temperature flexibility, high opacity, and successful vacuum collapse resistance further enhance their versatility.

About

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Morgan Heskett is a research engineer for Saint-Gobain Bioprocess Solutions, with a background in material science. Her work focuses on research and development support for Saint-Gobain's new and existing tubing product lines.

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Saint-Gobain Bioprocess Solutions

An industry-leading provider of materials science-based solutions for single-use fluid management, including TPE and silicone tubing, connection and flow control components, bioprocess and cell culture bags, filtration products, sensors, and over-molded technology, all available in customized assemblies that are produced in 19 manufacturing facilities located around the world.

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